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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/510,560 | 02/22/2000 | Kenneth Iain Cumming | 00.1090.US | 3011 |

7590 03/18/2005

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EXAMINER

CELSA, BENNETT M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

ELECTION of SPECIES

Office Action Summary

Application No.

09/510,560

Applicant(s)

CUMMING ET AL.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,39,41,42,47 and 49-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,41, 42, 47 and 49-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/04 has been entered.

In applicant's RCE request, several claims were amended (e.g. addressing blend combinations) and new claims presented (e.g. new claims 67-86 directed to Markush and individual drug species). In light of applicant's amendment, the newly presented claims and upon further consideration, the following election of species is being instituted in order to expedite prosecution and to better address those issues pointed to by applicant in the RCE response.

It is noted that the art rejections of record in light of applicant's arguments will be reconsidered in the next office action.

NOTE: the present application is now assigned to BENNETT CELSA, Primary Examiner , Art Unit 1639 (see below for information regarding future correspondences.

Status of the Claims

Claims 1, 3, 39, 41,42, 47, 49-86 are currently pending.

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Election/Restrictions

1. Claims 1, 3, 39, 41,42, 47, 49-86 comprise the recitation of composition/methods reciting multiply genres of compounds (and combinations thereof), each generic drawn to a plurality of disclosed patentably distinct species comprising:

A. "DRUG" (e.g. heparin or TRH or alendronate etc.);

B. "Salt of a medium chain (C6-20) fatty Acid" ;

C. Different Blend Combinations (e.g. see claim 47) comprising different "medium chain fatty acid derivatives" (e.g. "halide and/or anhydride and/or glyceride" or combinations thereof (e.g. "at the end opposite of the anhydride , an acid anhydride, acid halide, or glyceride)).

Both the search and the examination of a large number of claims drawn to a large number of different Drugs, medium chain(C6-20) fatty acids and/or fatty acid derivatives which differ in chemical structure, function, properties and which are capable of different methods of making and use is unduly burdensome since these claimed embodiments require different and separately burdensome manual/computer chemical name, structure and bibliographic searches in different patent and literature areas and databases; and additionally a reference applicable against one compound (or combination of compounds) is not necessarily applicable for prior art purposes against a different compound (or combination of compounds). Additionally, the different embodiments may raise different examination issues under 35 USC 112.

ACCORDINGLY: Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for EACH of items A. B. and C. above even though this requirement is traversed.

For example, applicant must elect:

A. A SINGLE DRUG COMPOUND DEFINABLE BY NAME OR CHEMICAL STRUCTURE ;

B. A SINGLE "MEDIUM CHAIN FATTY ACID AND CORRESPONDING SALT";

C. A SINGLE COMBINATION: COMPRISING THE SINGLE "MEDIUM CHAIN FATTY ACID AND CORRESPONDING SALT" OF ELECTED ITEM B AND A SECOND (2nd) DEFINED (E.G. A SINGLE COMPOUND DEFINED BY STRUCTURE OR CHEMICAL NAME) FATTY ACID DERIVATIVE COMPOUND.

IN ORDER TO BE COMPLETELY RESPONSIVE, APPLICANT MUST INDICATE CLAIMS WHICH ARE READABLE ON THE ELECTED INVENTION.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

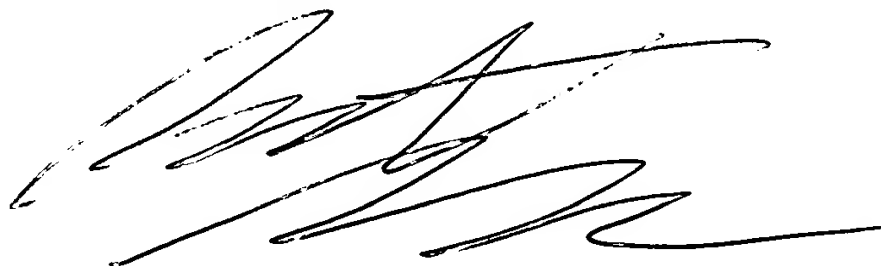
Future Correspondence:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
March 10, 2005